# EPA Registration No. 70506-93 vol. 2

# MATERIAL TO BE ADDED TO JACKET

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Division:



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

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United Phosphorus Inc. c/o N. Bhushan Mandava Ph.D. Mandava Associates, LLC 1730 M Street NW Washington, DC 20036

#### Gentlemen:

Subject:

New Source of Active Ingredient

Clopyralid Technical

EPA Registration No. 70506-93

Your applications Dated July 9, 2007 and August 31, 2007

The subject alternate formula is acceptable and has been included in the files for this product.

If you have any questions concerning this letter please contact Mr. James Stone at 703-305-7391.

Sincerely yours,

Kathryn V. Montague

Acting Product Manager (23)

Herbicide Branch

Registration Division (7505P)

FEE

DATE: 10/23/07

SUBJECT: Product Chemistry Review of CLOPYRALID TECHNICAL

FROM:

Indira Gairola

Product Chemistry Team

Technical Review Branch/RD (7505P)

TO:

Joanne Miller/James Stone PM 23 Herbicide Branch/RD (7505P)

DP BARCODE No.: 342015

File Symbol No.: 70506-93

COMPANY: UNITED PHOSPHORUS INC.

PCC: 117403

Decision No. 381191

Chemical Name: (IUPAC, ANSI, etc.) Clopyralid

CAS No.

1702-17-6

USE:

Herbicide

#### INTRODUCTION:

UNITED PHOSPHORUS INC. has submitted Product Chemistry Guideline reference 830 Subgroup A & B data to support the registration of new alternate source of active ingredient Clopyralid Technical.

Sym 10. 53-0

Details are listed below:

#### SUMMARY OF FINDINGS:

- Applicant UNITED PHOSPHORUS INC. has submitted MRID#s 471788-01,-03,-04,-05,-06, -07 and 471834-01 for Product Chemistry data to support the aforementioned registration of Clopyralid Technical.
- 2. The submitted package was reviewed and details of product chemistry data will be discussed in the following Pages:
- 3. The Alternate source Formulation CSF dated 07/09/07 is filled out completely and correctly.
- 4. The certified limits are in compliance with 40 CFR158 .175 (b) (2).

5. Average recovery of Clopyralid Technical ranged from acceptable level of 96.31%-97.04% Mean Average = 96.85%.

#### **CONLUSIONS:**

TRB has reviewed the product chemistry data submitted for the above mentioned subject product and has concluded that:

- 1. Product Chemistry data requirements for subgroup A are satisfactory and fulfill the requirement of OPP test guidelines.
- 2. Certified limits are in compliance with 40CFR.175 (b) (2). See CONFIDENTIAL APPENDIX.
- 3. Average recovery of Clopyralid Technical ranged from acceptable level of 96.31%-97.04% Mean Average =96.85%.
- 4. Alternate source Formulation CSF dated 07/09/07 is acceptable.
- 5. The impurity profile for the Alternate source Formulation CSF dated 07/09/07 is identical to the Basic Formulation CSF dated 01/15/03.
- 6. Product Chemistry data requirements for subgroup B completely fulfill the requirement of OPP test guidelines.

Sub Group 'A' Guidelines Series 830.1550-1800 DP BAR CODE: 342015 File Symbol No.: 70506-93 PRODUCT NAME: CLOPYRALID TECHNICAL

GLN	Requirement	MRID	Status¹	Details and/or Deficiency <sup>2</sup>	
830.1550	Product Identity & Disclosure of Ingredients		A	07/09/07	
830.1600 830.1620 830.1650	Starting Materials & Manufacturing Process		A	MRID # 471788-01	
830.1670	Discussion of Impurities		A	MRID # 471788-01	
830.1700	Preliminary Analysis		A	MRID # 471788-01	
830.1750	Certification of Limits		А	07/09/07	
830.1800	Analytical Methods		A	MRID # 471834-01	

GLN	Requirement	MRID.	Status <sup>1</sup>	Result <sup>2</sup> or Deficiency
830 .6 302	Color	471788-07	А	Off white
830.6303	Physical State	471788-07	A	Solid (powder)
830.6304	Odor	471788-07	A	Odorless
830.6313	Stability		N/A	Not determined since it is an alternate source.
830.631 4	Oxidation / Reduction		N/A	Not determined since it is an alternate source.
830.6315	Flammability	NA	NA	Not flammable
830.6316	Explodability	<u> </u>	N/A	
830.6317	Storage Stability	NA	NA	
830.6319	Miscibility	NA	NA	
830.6320	Corrosion Characteristics	NA	NA	
830.7000	pH	471788-07	A	1.75 (10% soln. in water)
830.7050	UV/Visible Absorption	·	N/A	Not determined since it is an alternate source.
	Viscosity	NA	NA	It is solid
830.7200	Melting Point/ Melting Range	471788-07	А	151-152°C
830.7220	Boiling Point/ Boiling Range	NA	NA	
830.7300	Density/ Relative Density/ Bulk Density	471788-07	A	Pour 0.46g/mL@25 °C, Relative density 1.58 @20°C
830.7370	Dissociation Constant in Water	471788-07	N/A	Not determined since it is an alternate source.
830.7550	Partition Coefficient (Octanol/Water)			Log <sub>10</sub> K <sub>ow)</sub> @ 20 °C
830.7840	Solubility	471788-07		143 g/L in water.@pH7, @20°C,12.2 in Acetonitrile, 10.6 methanol, 0.6 Hexane, 39.6 N- Methyl pyrrolidone, 13.1 Octanol @ 20°C
830.7950	Vapor Pressure	471788-07		1.35 m Pa@25°C

<sup>&</sup>lt;sup>1</sup> A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not applicable, I= incomplete

#### Product Identity [OPPTS Guideline 830.1500 (OPP Guideline 61-1)]

Information on the product identity and composition of the pesticide product is covered under 40 CFR §158.155. The information required, among others, includes the source (if applicable), chemical and common names, CAS Registry Number and the identity of each ingredient in the Technical Grade of the Active Ingredient (TGAI) if it is a mixture.

The following information is provided to satisfy this guideline requirement:

Product Identity and Composition [40 CFR §158.155; OPPTS Guideline 830.1550 (OPP Guideline 61-1)

Common Name:

Clopyralid (ISO Draft, ANSI and BSI)

Chemical name:

3,6-Dichloro-2-pyridinecarboxylic acid (CAS)

Synonyms:

3,6-Dichloropicolinic acid (IUPAC)

3,6-Dichloropyridine-2-carboxylic acid

Experimental Code:

None

CAS Reg. No.:

1702-17-6

EPA Chemical Code: 117403

Molecular Formula: C<sub>6</sub>H<sub>3</sub>Cl<sub>2</sub>NO<sub>2</sub>

Molecular Weight:

192

Chemical Structure:

SUB GROUP A

I MANUFACTURING PROCESS (830.1620):

For details please refer to the CONFIDENTIAL APPENDIX.

II DISCUSSION OF FORMATION OF IMPURITIES (830.1670):

This portion will be discussed in CONFIDENTIAL APPENDIX

III PRELIMINARY ANALYSES 830.1700. This portion will be discussed in CONFIDENTIAL APPENDIX

#### **1V CERTIFIED LIMITS**

Please refer to the CONFIDENTIAL APPENDIX for CSF.

V. ENFORCEMENT ANALYTICAL METHOD (830.1800)





#### **DATA PACKAGE BEAN SHEET**

Date: 26-Jul-2007 Page 1 of 2

Decision #: 381191

DP #: (342015)

PRIA

#### \* \* \* Registration Information \* \* \*

		Page 1 of	2	F	Parent DP#:	
Registration:	* * * 70506-93 - AGVALUE	Registration Inf		•	R34	2164
Company:	70506 - UNITED PHOSPH	ORUS, INC			#2	2166
Risk Manager:	RM 23 - Joanne Miller - (70	03) 305-6224 Room# PY1	I S-7328		XI 9	,
sk Manager Reviewer:	James Stone JSTONE	178 - 1114		_		
Sent Date:	23-Jul-2007	Calculated Due Da	te: 30-Nov-2007 /	Edite	d Due Date:	
Type of Registration:	Product Registration - Sect	tion 3				
Action Desc:	(R34) NON-FAST-TRACK	(INCLUDES CHANGES	TO PRECAUTIONAL	RY LABEL STATEM	EN	
Ingredients:	117403, Clopyralid(96%)					
	Yes ■ No 117403, Clopyralid	Date Se	nt: 26-Jul-2007		Due Back:	-
DP Title:					_	
CSF Included:	Yes No La	abel Included: Yes	No Parent	DP #:	_	
Assigned To	0	Date In	Date Out			
Organization: RD / T	RB			ast Possible Scienc	e Due Date: 31-Oct-2007	
Team Name: CHEM	1			Science	e Due Date:	
Reviewer Name:				Sub Data Packag	e Due Date:	
ontractor Name:						

#### \* \* \* Studies Sent for Review \* \* \*

Printed on Page 2

#### \* \* \* Additional Data Package for this Decision \* \* \*

No Additional Data Packages

\* \* \* Data Package Instructions \* \* \*

Review product chemistry data to support new alternate unregistered source of active ingredient.



\* \* \* Studies Sent for Review \* \* \*

( ,		Studies Selit for Keview	Decisionim. (501181)
MRID	MRID Status	Citation Reference	Guideline
47178803		Mandava, N. (2007) Clopyralid Technical: Group A - Product	830.1750/Certified limits
		Identity, Composition and Analysis. Project Number: UPL/CLOPYR/TECH/PC/2. Unpublished study prepared by United Phosphorus, Inc. 35 p.	
47178803		Mandava, N. (2007) Clopyralid Technical: Group A - Product Identity, Composition and Analysis. Project Number: UPL/CLOPYR/TECH/PC/2. Unpublished study prepared by United Phosphorus, Inc. 35 p.	830.1800/Enforcement analytical method
47178803		Mandava, N. (2007) Clopyralid Technical: Group A - Product Identity, Composition and Analysis. Project Number: UPL/CLOPYR/TECH/PC/2. Unpublished study prepared by United Phosphorus, Inc. 35 p.	830.7560/Partition coefficient (n-octanol/water), generator column method
47178804		Desai, H. (2007) Appearance (Colour, Physical State and Odour) of Clopyralid Technical. Project Number: 6592. Unpublished study prepared by Jai Research Foundation. 25 p.	830.6302/Color
47178804		Desai, H. (2007) Appearance (Colour, Physical State and Odour) of Clopyralid Technical. Project Number: 6592. Unpublished study prepared by Jai Research Foundation. 25 p.	830.6303/Physical state
47178804		Desai, H. (2007) Appearance (Colour, Physical State and Odour) of Clopyralid Technical. Project Number: 6592. Unpublished study prepared by Jai Research Foundation. 25 p.	830.6304/Odor
47178805		Parmar, J. (2007) pH of Clopyralid Technical. Project Number: 6593. Unpublished study prepared by Jai Research Foundation. 27 p.	830.7000/pH of water solutions or suspensions
47178806		Desai, H. (2007) Tap Density of Clopyralid Purified. Project Number: 6661, CIPAC/MT/33. Unpublished study prepared by Jai Research Foundation. 24 p.	
47178807		Mandava, N. (2007) Clopyralid Technical: Group B - Physical and Chemical Properties. Project Number: UPL/CLOPYR/TECH/PC/3. Unpublished study prepared by	111-222/
	•	United Phosphorus, Inc. 10 p.	
47178807		Mandava, N. (2007) Clopyralid Technical: Group B - Physical and Chemical Properties. Project Number: UPL/CLOPYR/TECH/PC/3. Unpublished study prepared by	830.6302/Color
47178807		United Phosphorus, Inc. 10 p. Mandava, N. (2007) Clopyralid Technical: Group B - Physical and	930 6303/Physical state
47170007		Chemical Properties. Project Number: UPL/CLOPYR/TECH/PC/3. Unpublished study prepared by United Phosphorus, Inc. 10 p.	650.0505/Filysical state
47178807		Mandava, N. (2007) Clopyralid Technical: Group B - Physical and Chemical Properties. Project Number: UPL/CLOPYR/TECH/PC/3. Unpublished study prepared by United Phosphorus, Inc. 10 p.	830.6304/Odor
47178807		Mandava, N. (2007) Clopyralid Technical: Group B - Physical and Chemical Properties. Project Number: UPL/CLOPYR/TECH/PC/3. Unpublished study prepared by	830.6313/Stability to sunlight, normal and elevated temperatures, metals, and metal ions
47178807		United Phosphorus, Inc. 10 p. Mandava, N. (2007) Clopyralid Technical: Group B - Physical and Chemical Properties. Project Number: UPL/CLOPYR/TECH/PC/3. Unpublished study prepared by	830.6314/Oxidizing or reducing action
47178807		United Phosphorus, Inc. 10 p.  Mandava, N. (2007) Clopyralid Technical: Group B - Physical and Chemical Properties. Project Number:  UPL/CLOPYR/TECH/PC/3. Unpublished study prepared by	830.6315/Flammability
47178807		United Phosphorus, Inc. 10 p.  Mandava, N. (2007) Clopyralid Technical: Group B - Physical and Chemical Properties. Project Number:  UPL/CLOPYR/TECH/PC/3. Unpublished study prepared by	830.6317/Storage stability of product
47178807		United Phosphorus, Inc. 10 p.  Mandava, N. (2007) Clopyralid Technical: Group B - Physical and Chemical Properties. Project Number:  UPL/CLOPYR/TECH/PC/3. Unpublished study prepared by	830.6319/Miscibility
47178807		United Phosphorus, Inc. 10 p.  Mandava, N. (2007) Clopyralid Technical: Group B - Physical and Chemical Properties. Project Number:  UPL/CLOPYR/TECH/PC/3. Unpublished study prepared by	830.6320/Corrosion characteristics
47178807		United Phosphorus, Inc. 10 p.  Mandava, N. (2007) Clopyralid Technical: Group B - Physical and Chemical Properties. Project Number:  UPL/CLOPYR/TECH/PC/3. Unpublished study prepared by	830.6321/Dielectric breakdown voltage
47178807		United Phosphorus, Inc. 10 p.  Mandava, N. (2007) Clopyralid Technical: Group B - Physical and Chemical Properties. Project Number:  UPL/CLOPYR/TECH/PC/3. Unpublished study prepared by	830.7000/pH of water solutions or suspensions

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\* \* \* Studies Sent for Review \* \* \*

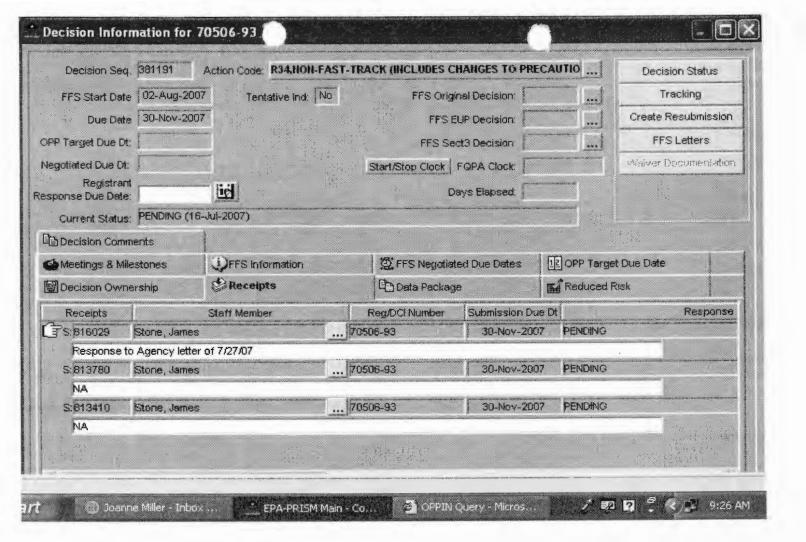
MRID **MRID Status** Citation Reference Guideline 47178801 Mandava, N. (2007) Clopyralid Technical: Group A - Product 63-0/Reports of Multiple phys/chem Identity, Composition and Analysis. Project Number: Characteristics UPL/CLOPYR/TECH/PC/1. Unpublished study prepared by United Phosphorus, Inc. 109 p. Mandava, N. (2007) Clopyralid Technical: Group A - Product 830.1550/Product Identity and 47178801 Identity, Composition and Analysis. Project Number: composition UPL/CLOPYR/TECH/PC/1. Unpublished study prepared by United Phosphorus, Inc. 109 p. Mandava, N. (2007) Clopyralid Technical: Group A - Product 830.1600/Description of materials 47178801 Identity, Composition and Analysis. Project Number: used to produce the product UPL/CLOPYR/TECH/PC/1. Unpublished study prepared by United Phosphorus, Inc. 109 p. Mandava, N. (2007) Clopyralid Technical: Group A - Product 830.1620/Description of production 47178801 Identity, Composition and Analysis. Project Number: process UPL/CLOPYR/TECH/PC/1. Unpublished study prepared by United Phosphorus, Inc. 109 p. 47178801 Mandava, N. (2007) Clopyralid Technical: Group A - Product 830.1650/Description of formulation Identity, Composition and Analysis. Project Number: process UPL/CLOPYR/TECH/PC/1. Unpublished study prepared by United Phosphorus, Inc. 109 p. 47178801 Mandava, N. (2007) Clopyralid Technical: Group A - Product 830.1670/Discussion of formation of Identity, Composition and Analysis. Project Number: impurities UPL/CLOPYR/TECH/PC/1. Unpublished study prepared by United Phosphorus, Inc. 109 p. Mandava, N. (2007) Clopyralid Technical: Group A - Product 47178801 830.1700/Preliminary analysis Identity, Composition and Analysis. Project Number: UPL/CLOPYR/TECH/PC/1. Unpublished study prepared by United Phosphorus, Inc. 109 p. Mandava, N. (2007) Clopyralid Technical: Group A - Product 830.1750/Certified limits 47178801 Identity, Composition and Analysis. Project Number: UPL/CLOPYR/TECH/PC/1. Unpublished study prepared by United Phosphorus, Inc. 109 p. Mandava, N. (2007) Clopyralid Technical: Group A - Product 830.1800/Enforcement analytical 47178801 Identity, Composition and Analysis. Project Number: method UPL/CLOPYR/TECH/PC/1. Unpublished study prepared by United Phosphorus, Inc. 109 p. Mandava, N. (2007) Clopyralid Technical: Group A - Product 830.6302/Color 47178801 Identity, Composition and Analysis. Project Number: UPL/CLOPYR/TECH/PC/1. Unpublished study prepared by United Phosphorus, Inc. 109 p. Mandava, N. (2007) Clopyralid Technical: Group A - Product 830.6303/Physical state 47178801 Identity, Composition and Analysis. Project Number: UPL/CLOPYR/TECH/PC/1. Unpublished study prepared by United Phosphorus, Inc. 109 p. Mandava, N. (2007) Clopyralid Technical: Group A - Product 830.7560/Partition coefficient 47178801 Identity, Composition and Analysis. Project Number: UPL/CLOPYR/TECH/PC/1. Unpublished study prepared by (n-octanol/water), generator column method United Phosphorus, Inc. 109 p. 47178803 Mandava, N. (2007) Clopyralid Technical: Group A - Product 63-0/Reports of Multiple phys/chem Identity, Composition and Analysis. Project Number: Characteristics UPL/CLOPYR/TECH/PC/2. Unpublished study prepared by United Phosphorus, Inc. 35 p. Mandava, N. (2007) Clopyralid Technical: Group A - Product 830.1550/Product Identity and 47178803 Identity, Composition and Analysis. Project Number: UPL/CLOPYR/TECH/PC/2. Unpublished study prepared by composition United Phosphorus, Inc. 35 p. Mandava, N. (2007) Clopyralid Technical: Group A - Product 830.1600/Description of materials 47178803 Identity, Composition and Analysis. Project Number: used to produce the product UPL/CLOPYR/TECH/PC/2. Unpublished study prepared by United Phosphorus, Inc. 35 p. Mandava, N. (2007) Clopyralid Technical: Group A - Product 830.1620/Description of production 47178803 Identity, Composition and Analysis. Project Number: process UPL/CLOPYR/TECH/PC/2. Unpublished study prepared by United Phosphorus, Inc. 35 p. Mandava, N. (2007) Clopyralid Technical: Group A - Product 830.1650/Description of formulation 47178803 Identity, Composition and Analysis. Project Number: process UPL/CLOPYR/TECH/PC/2. Unpublished study prepared by United Phosphorus, Inc. 35 p. Mandava, N. (2007) Clopyralid Technical: Group A - Product 830.1670/Discussion of formation of 47178803 Identity, Composition and Analysis. Project Number: impurities UPL/CLOPYR/TECH/PC/2. Unpublished study prepared by United Phosphorus, Inc. 35 p. Mandava, N. (2007) Clopyralid Technical: Group A - Product 830.1700/Preliminary analysis 47178803 Identity, Composition and Analysis. Project Number: UPL/CLOPYR/TECH/PC/2. Unpublished study prepared by United Phosphorus, Inc. 35 p.

Decision#: (381191)

#### \* \* \* Studies Sent for Review \* \* \*

Decision#: (381191) MRID Status MRID Citation Reference Guideline 47178801 Mandava, N. (2007) Clopyralid Technical: Group A - Product 63-0/Reports of Multiple phys/chem Identity, Composition and Analysis. Project Number: Characteristics UPL/CLOPYR/TECH/PC/1. Unpublished study prepared by United Phosphorus, Inc. 109 p. 47178801 Mandava, N. (2007) Clopyralid Technical: Group A - Product 830.1550/Product Identity and Identity, Composition and Analysis. Project Number: composition UPL/CLOPYR/TECH/PC/1. Unpublished study prepared by United Phosphorus, Inc. 109 p. Mandava, N. (2007) Clopyralid Technical: Group A - Product 47178801 830.1600/Description of materials Identity, Composition and Analysis. Project Number: used to produce the product UPL/CLOPYR/TECH/PC/1. Unpublished study prepared by United Phosphorus, Inc. 109 p. Mandava, N. (2007) Clopyralid Technical: Group A - Product 47178801 830.1620/Description of production Identity, Composition and Analysis. Project Number: process UPL/CLOPYR/TECH/PC/1. Unpublished study prepared by United Phosphorus, Inc. 109 p. 47178801 Mandava, N. (2007) Clopyralid Technical: Group A - Product 830.1650/Description of formulation Identity, Composition and Analysis. Project Number: UPL/CLOPYR/TECH/PC/1. Unpublished study prepared by process United Phosphorus, Inc. 109 p. Mandava, N. (2007) Clopyralid Technical: Group A - Product 47178801 830.1670/Discussion of formation of Identity, Composition and Analysis. Project Number: impurities UPL/CLOPYR/TECH/PC/1. Unpublished study prepared by United Phosphorus, Inc. 109 p. Mandava, N. (2007) Clopyralid Technical: Group A - Product 47178801 830.1700/Preliminary analysis Identity, Composition and Analysis. Project Number: UPL/CLOPYR/TECH/PC/1. Unpublished study prepared by United Phosphorus, Inc. 109 p. Mandava, N. (2007) Clopyralid Technical: Group A - Product 47178801 830.1750/Certified limits Identity, Composition and Analysis. Project Number: UPL/CLOPYR/TECH/PC/1. Unpublished study prepared by United Phosphorus, Inc. 109 p. Mandava, N. (2007) Clopyralid Technical: Group A - Product 47178801 830.1800/Enforcement analytical Identity, Composition and Analysis. Project Number: method UPL/CLOPYR/TECH/PC/1. Unpublished study prepared by United Phosphorus, Inc. 109 p. Mandava, N. (2007) Clopyralid Technical: Group A - Product 47178801 830.6302/Color Identity, Composition and Analysis. Project Number: UPL/CLOPYR/TECH/PC/1. Unpublished study prepared by United Phosphorus, Inc. 109 p. Mandava, N. (2007) Clopyralid Technical: Group A - Product 830.6303/Physical state 47178801 Identity, Composition and Analysis. Project Number: UPL/CLOPYR/TECH/PC/1. Unpublished study prepared by United Phosphorus, Inc. 109 p. Mandava, N. (2007) Clopyralid Technical: Group A - Product 47178801 830.7560/Partition coefficient Identity, Composition and Analysis. Project Number: UPL/CLOPYR/TECH/PC/1. Unpublished study prepared by (n-octanol/water), generator column method United Phosphorus, Inc. 109 p. Mandava, N. (2007) Clopyralid Technical: Group A - Product 47178803 63-0/Reports of Multiple phys/chem Identity, Composition and Analysis. Project Number: Characteristics UPL/CLOPYR/TECH/PC/2. Unpublished study prepared by United Phosphorus, Inc. 35 p. Mandava, N. (2007) Clopyralid Technical: Group A - Product 830.1550/Product Identity and 47178803 Identity, Composition and Analysis. Project Number: composition UPL/CLOPYR/TECH/PC/2. Unpublished study prepared by United Phosphorus, Inc. 35 p. Mandava, N. (2007) Clopyralid Technical: Group A - Product 830.1600/Description of materials 47178803 Identity, Composition and Analysis. Project Number: used to produce the product UPL/CLOPYR/TECH/PC/2. Unpublished study prepared by United Phosphorus, Inc. 35 p. Mandava, N. (2007) Clopyralid Technical: Group A - Product 830.1620/Description of production 47178803 Identity, Composition and Analysis. Project Number: process UPL/CLOPYR/TECH/PC/2. Unpublished study prepared by United Phosphorus, Inc. 35 p. 47178803 Mandava, N. (2007) Clopyralid Technical: Group A - Product 830.1650/Description of formulation Identity, Composition and Analysis. Project Number: process UPL/CLOPYR/TECH/PC/2. Unpublished study prepared by United Phosphorus, Inc. 35 p. Mandava, N. (2007) Clopyralid Technical: Group A - Product 830.1670/Discussion of formation of 47178803 Identity, Composition and Analysis. Project Number: impurities UPL/CLOPYR/TECH/PC/2. Unpublished study prepared by United Phosphorus, Inc. 35 p. Mandava, N. (2007) Clopyralid Technical: Group A - Product 830.1700/Preliminary analysis 47178803 Identity, Composition and Analysis. Project Number: UPL/CLOPYR/TECH/PC/2. Unpublished study prepared by

United Phosphorus, Inc. 35 p.



Resub.

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## MANDAVA ASSOCIATES, LLC

CONSULTANTS IN SCIENCE, TECHNOLOGY AND REGULATORY AFFAIRS
1730 M STREET, N.W., SUITE 906, WASHINGTON, DC 20036-4549
TELEPHONE: (202)-223-1424/1747 · TELEFAX: (202)-223-0141 · E-MAIL:mandava@compuserve.com

#### HAND DELIVERED

August 31, 2007

Ms. Joanne I. Miller
Product Manager (PM 23)
U.S. Environmental Protection Agency
Office of Pesticide Programs
Herbicide Branch
Registration Division (7505P)
Room Number 4900
2777 S. Crystal Drive
Arlington, VA 22202

SUBJECT: Clopyralid Technical – Approval of Alternate Source

Company: United Phosphorus, Inc.

EPA Reg. No.: 70506-93 Response to EPA Comments

Dear Ms. Miller:

This is in response to your July 27, 2007 letter regarding a New Source of Active Ingredient for Clopyralid Technical (EPA Reg. No.: 70506-93) by United Phosphorus, Inc. You requested us to provide the following information:

- 1) Submit a notarized letter on company letter head authorizing N. Bhushan Mandava, Ph.D. to handle all registration matters for the subject product.
  - a. We understand that Dr. David L. Olson, Director, Regulatory Affairs, United Phosphorus, Inc. has emailed you the letter on August 9, 2007 and we are submitting a copy along with this letter for your ready reference.
- 2) Adding a new unregistered source of active ingredient is subject to data compensation. You must comply with Title 40 Code of Federal Regulations (CFR) Part 152 Subpart E Procedures to Ensure Protection of Data Submitter's Rights by choosing the Cite-All or the Selective Methods of Support. Submit a Certificate with Respect to Citation of Data (EPA Form 8570-34) and a Data Matrix (EPA Form 8570-27).

Since we are not aware of this requirement, I discussed it with Mr. James Stone on August 28, 2007 over the telephone. In our opinion, the product is already registered and all issues related to data compensation were addressed and satisfied at the time of registration. For granting the registration for Clopyralid Technical (EPA Reg. No.: 70506-93), the Agency reviewed the product specific data to ensure the quality of the product which met the substantial similarity (or ME-TOO) criteria.

For alternate source (unregistered source), our understanding is that the Agency requires only product chemistry data to compare the quality of the unregistered source product to that of the currently registered source product for Clopyralid Technical (EPA Reg. No. 70506-93). It is also our understanding that the Agency has been approving alternate sources (unregistered sources) for registered products provided that the product quality (purity of the active ingredient and impurity profile) remains the same or substantially similar to that of the registered source(s). We are not aware that the Agency requires the applicants/registrants to comply with 40 CFR Part 152 Subpart E whenever they seek new (alternate) sources. We would appreciate it very much if you would supply us a copy of the guidance document (based on an internal policy statement or a letter from Office of General Counsel) in support of this requirement.

Since the submission is subject to PRIA, we do not want to delay the registration process. Therefore, we are submitting the requested information which includes Certificate with Respect to Citation of Data (EPA Form 8570-34) and a completed Data Matrix (EPA Form 8570-27).

Thank you for your cooperation and understanding.

Sincerely,

N. Bhushan Mandava, Ph.D., RAC Agent for United Phosphorus, Inc.

N. Bhushan Mandage

Agent for United Phosphorus, Inc.

Enclosure



### **United Phosphorus, Inc.**

630 Freedom Business Center, Suite 402 King of Prussia, PA 19406 (610) 491-2814 (phone) (610) 491-2810 (fax)

August 9, 2007

Joanne Miller, PM #23 Office of Pesticide Programs U.S. Environmental Protection Agency 1200 Pennsylvania Avenue, NW Washington, DC 20460

SUBJECT: Authorization Letter

Dear Ms. Miller

This letter is to authorize the following party to act on behalf of United Phosphorus Inc. as our agent to represent us before the United States Environmental Protection Agency (EPA) in regards to all matters pertaining to the registration of an alternate source for Clopyralid Technical (EPA Reg. # 70506-93). This authorization is specific to this regulatory action, which was submitted to the Agency on July 9, 2007.

MANDAVA ASSOCIATES, LLC 1730 M Street, N.W. Suite 906 Washington, DC 20036-4510 Telephone: (202) 223-1424

Fax: (202) 223-0141

E-Mail: Mandava@compuserve.com

Contact Person: N. Bhushan Mandava, Ph.D.

We acknowledge that all correspondence from EPA will be sent to our agent at the address listed above.

This appointment is to remain in effect until revoked by us in writing.

Sincerely,

David L. Olson

Director, Regulatory Affairs dave.olson@uniphos.com

Please read instructions on re	verse before con.	ng form.		Form Approve	OMB No. 207	0-0060	Approval expires 2-28-95
<b>⊕EPA</b>	Environmental	nited States Protection ngton, DC 2046		~	Registration Amendment Other		OPP Identifier Number
		Application	for Pesticio	le - Section	l	<u> </u>	
1. Company/Product Number 70506-93			2. EPA F	Product Manager ne I. Miller			posed Classification None Restricted
4. Company/Product (Name) United Phosphorus, Inc	c./Clopyralid Tech	nical	PM# 23				Nostricited
5. Name and Address of Appl United Phosphorus, In 630 Freedom Busines King of Prussia, PA 19 Chack if this	c. s Center, Suite 4	·	(b)(i), m to: EPA R		ilar or identica	l in con	FIFRA Section 3(c)(3) nposition and labeling
	<del></del>		Section - I	<u> </u>		<u> </u>	
Amendment - Explain Resubmission in respo	nse to Agency letter pelow.			Final printed label Agency letter dat "Me Too" Applica Other - Explain be	ed ation.	)	
Explanation: Use additional The amendment is in responsing response to EPA comments, volume 1) Certification with Respect to 2) Data Matrix (EPA Form 8573) Please direct all corresponding to the contact person fax numbers.	e to EPA comments or we are submitting the fo o Citation of Data (EPA 0-35) dence to: Mandava Ass	n the registration ollowing: A Form 8570-34) sociates, LLC; 17	application for alte	Suite 906; Washing	,	`	eg. No. 70506-93). In
· -			Section - II	1	****		· · · · · · · · · · · · · · · · · · ·
1. Material This Product Will	Be Packaged In:					·	
Child-Resistant Packaging  Yes  No  Certification must be submitted	Unit Packaging Yes No If "Yes" Unit Packaging wgt.	No. per container	Water Soluble Power Soluble Po	No. per container		ntainer Metal Mestic Glass Paper Other (Sp	pecify)
3. Location of Net Contents In	nformation	4. Size(s) Retei	Container		cation of Lebel	Direction	)S
6. Manner in Which Label is A		Lithogra Paper gl Stencile	ph ued d	Other			
			Section - I	/			
1. Contact Point /Complete i	tems directly below f	or identification	of individual to be	contacted, if nec	essary, to proce	es this e	application.)
Name N. Bhushan Mandava, Ph.	D.	[ ]	itle Agent for United	Phosphorus, (nc.		dephone (02) 223-	No. (Include Area Code) 1424
I certify that the statem I acknowledge that any both under applicable is	knowlingly false or	Certificati this form and a misleading state	ii attachments the	reto are true, acci ishable by fine or	urate and compl imprisonment o	ete.	6. Date Application Received (Stamped)
2. Signature			. Title				
N. Bhusha	, Manda	ve /	Agent for United Ph	nosphorus, inc.			
4. Typed Name	_	5.	. Date	20/07			
N. Bhushan Mandava, Ph.(	J.	]	08/3	30/07		1	



#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460

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Information Management Division (2137), U.S. Environmental Protection Agency, 401 Do not send the completed form to this address.	M Street, S.W., Wa	shington, DC 20460.
Certification with Respect	to Citation of [	Data
Applicant's/Registrant's Name, Address, and Telephone Number United Phosphorus, Inc. 630 Freedom Center, Suite 402 King of Prussia, PA 19406	(610) 491-2800	EPA Registration Number/File Symbol 70506-93
Active Ingredient(s) and/or representative test compound(s) Clopyralid (CAS# 1702-17-6)		Date August 30, 2007
General Use Pattern(s) (list_all those claimed for this product using 40 CFR Part 158) TGAI, MUP		Product Name Clopyralid Technical
NOTE: If your product is a 100% repackaging of another purchased EPA-registered submit this form. You must submit the Formulator's Exemption Statement (EPA Form		r all the same uses on your label, you do not need to
I am responding to a Data-Call-In Notice, and have included with this form a libe used for this purpose).	ist of companies ser	nt offers of compensation (the Data Matrix form should
SECTION I: METHOD OF DATA SUPPO	ORT (Check one me	ethod only)
I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	under the	the selective method of support (or cite-all option selective method), and have included with this form a I list of data requirements (the Data Matrix form must be
SECTION II: GENERAL C	FFER TO PAY	
[Required if using the cite-all method or when using the cite-all option under the select  I hereby offer and agree to pay compensation, to other persons, with regard to		
SECTION III: CERTI	FICATION	
I certify that this application for registration, this form for reregistration, or thi application for registration, the form for reregistration, or the Data-Call-In response. In indicated in Section I, this application is supported by all data in the Agency's files that substantially similar product, or one or more of the ingredients in this product; and (2) is requirements in effect on the date of approval of this application if the application souguses.	addition, if the cite-a (1) concern the pro s a type of data that	all option or cite-all option under the selective method is perties or effects of this product or an identical or would be required to be submitted under the data
I certify that for each exclusive use study cited in support of this registration the written permission of the original data submitter to cite that study.	or reregistration, tha	at I am the original data submitter or that I have obtained
I certify that for each study cited in support of this registration or reregistration submitter; (b) I have obtained the permission of the original data submitter to use the stompensation have expired for the study; (d) the study is in the public literature; or (e) offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c) amount and terms of compensation, if any, to be paid for the use of the study.	study in support of the I have notified in wri	nis application; (c) all periods of eligibility for iting the company that submitted the study and have
I certify that in all instances where an offer of compensation is required, cop accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be evidence to the Agency upon request, I understand that the Agency may initiate action FIFRA.	e submitted to the A to deny, cancel or s	Agency upon request. Should I fail to produce such suspend the registration of my product in conformity with
I certify that the statemente I have made on this form and all attachm knowingly false or misleading statement may be punishable by fine or imprison	ents to it are true, nment or both und	accurate, and complete. I acknowledge that any ier applicable law.
Signature N. Bhushan Mandana	Date August 30, 2007	Typed or Printed Name and Title  N. Bhushan Mandava, Agent

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.



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	DA	TA MATRIX				
Date August 30, 2007	Date August 30, 2007			EPA Reg No./File Symbol 70506-93		
Applicant's/Registrant's Name & Address United Phosphorus, Inc. 630 Freedom Business Center, Suite 402 King of Prussia, PA 19406			Product Clopyralid Technical			
Ingredient Clopyralid (CAS# 1702	-17-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
830.1550	Product Identity and Composition		United Phosphorus, Inc. 630 Freedom Business	OWN	_	
			Ctr,,Ste 402 King of Prussia, PA 19406			
830.1600	Description of Materials Used to Produce the Product		United Phosphorus, Inc.	OWN		
830.1620	Description of Production Process		United Phosphorus, Inc.	OWN		
830.1650	Description of Formulation Process		United Phosphorus, Inc.	OWN		
830.1670	Discussion of Formation of Impurities		United Phosphorus, Inc.	OWN		
830.1700	Preliminary Analysis		United Phosphorus, Inc.	OWN		
B30.1750	Certified Limits		United Phosphorus, Inc.	OWN		
830.1800	Enforcement Analytical Method		United Phosphorus, Inc.	OWN		
830.6302	Color		United Phosphorus, Inc.	OWN		
830.6303	Physical State		United Phosphorus, Inc.	OWN		
830.6304	Odor		United Phosphorus, Inc.	OWN		
830.6313	Stability to Normal & Elevated Temperatures, Metals		United Phosphorus, Inc.	OWN		
	and Metal lons	T				
830.6314	Oxidation/Reduction: Chemical Incompatibility	Ī	United Phosphorus, Inc.	OWN		
Signature N · Ph	ushan Mandova		Name and Title  N. Bhushan Mandava, Ph.D., Agent - United Pho	osphorus, inc.	Date August 30, 200	

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Nate August 30, 2007					
Date August 30, 2007  Applicant's/Registrant's Name & Address  United Phosphorus, Inc. 630 Freedom Business Center, Suite 402 King of Prussia, PA 19406			EPA Reg No./File Symbol 70506-93	Page 2 of 7	
			Product Clopyralid Techical		
ngredient Clopyralid (CAS# 1702-17-6)	)				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
330.6315	Flammability		United Phosphorus, Inc.		Not Required
330.6316	Explodability		United Phosphorus, Inc.		Not Required
330.6317	Storage Stability		United Phosphorus, Inc.	OWN	
30.6319	Miscibility		United Phosphorus, Inc.	OWN	
330.6320	Corrosion Characteristics	i	United Phosphorus, Inc.	OWN	
330.6321	Dielectric Breakdown Voltage		United Phosphorus, Inc.	OWN	
330.7000	рН		United Phosphorus, Inc.	OWN	
30.7050	UV/Visible Absorption		United Phosphorus, Inc.	OWN	
30.7100	Viscosity		United Phosphorus, Inc.	OWN	
30.7200	Melting Point/Melting Range		United Phosphorus, Inc.	OWN	
30.7220	Boiling Point/Boiling Range		United Phosphorus, Inc.	OWN	
330.7300	Density/Relative Density/Bulk Density		United Phosphorus, Inc.	OWN	
30.7370	Dissociation Constants in Water		United Phosphorus, Inc.	OWN	
30.7550	Partition Coefficient (n-octanol/water), Shake Flask Method		United Phosphorus, Inc.	OWN	
Signature N Bhusha	u Mandara		Name and Title  N. Bhushan Mandava, Ph.D., Agent - United Ph	osphorus Inc	Date August 30, 2007

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	1	DATA MATRIX			
Date August 30, 2007		EPA Reg No./File Symbol 70506-93	Page 3 of 7		
Applicant's/Registrant's Name & Address United Phosphorus, Inc. 630 Freedom Business Center, Suite 402 King of Prussia, PA 19406			Product Clopyralid Technical		
Ingredient Clopyralid (CAS# 1702	-17-6)				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7560	Partition Coefficient (n-octanol/water),		United Phosphorus, Inc.	OWN	
	Generator Column Method				
830.7570	Partition Coefficient (n-octanol/water),		United Phosphorus, Inc.	OWN	
	Estimation by Liquid Chromatography				
830.7840	Water Solubility: Column Elution Method;		United Phosphorus, Inc.	OWN	
	Shake Flask Method				
830.7860	Water Solubility, Generator Column Method		United Phosphorus, Inc.	OWN	
830.7950	Vapor Pressure		United Phosphorus, Inc.	OWN	
		i			
Signature W. BU	urban Mandava		Name and Title  N. Bhushan Mandava, Ph.D., Agent - Ui	nited Phosphorus, Inc.	Date August 30, 200

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		DATA MATRIX			
Date August 30, 2007			EPA Reg No./File Symbol 70506-93		Page 4 of 7
Applicant's/Registrant's Name & Address United Phosphorus, Inc. 630 Freedom Business Center, Suite 402 King of Prussia, PA 19406		Product Ciopyralid Technical			
Ingredient Clopyralid (CAS# 1702-1	7-6)				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Acute Toxicity and Generic Data		CITE-ALL	Bayer CropScience, LP	Pay	
·—·			2 T.W. Alexander Drive Research		
			Triangle Park, NC 27709 (Company # 264)		
			Bayer Environmental Science	Pay	
			A Business Group of Bayer Cropscience LP		
			P O Box 12014 Research		
			Triangle Park, NC 27709 (Company # 432)		
			Osmcse Inc.	Pay	
			980 Ellicot Street		
			Buffalo, NY 14209 (Company # 3008)		
<del>_</del>			Bayer Corp. P.O. Box 4913	Pay	
<del>-</del>			Kansas City, MO 641200013 (Company # 3125)		
			Cerexagri, Inc.	Pay	
			630 Freedom Business Center, Suite 402		
· · · · · · · · · · · · · · · · · · ·			King of Prussia, PA 19406 (Company # 4581)		
Signature W. Z.L.	man Mandove	<u> </u>	Name and Title  N. Bhushan Mandava, Ph.D., Agent - United Pho	osphorus, Inc	Date August 30, 200

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		DATA MATRIX			
Date August 30, 2007			EPA Reg No./File Symbol 70506-93	Page 5 of 7	
Applicant's/Registrant's Name & Address United Phosphorus, Inc. 630 Freedom Business Center, Suite 402 King of Prussia, PA 19406		Product Clopyralid Technical			
Ingredient Clopyralid (CAS# 1702-17	7-6)				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Acute Toxicity and Generic Data		CITE-ALL	Dow Chemical Co., The	Pay	
			1500 East Lake Cook Road		
			Buffalo Grove, IL 60089 (Company # 464)		<u> </u>
			NuFarm Americas Inc.	Pay	
			150 Harvester Drive, Suite 200		
			Burr Ridge, IL 60527 (Company # 228)		
			Lebanon Seaboard Corporation	Pay	
			1600 East Cumberland Street		
			Lebanon, PA 17402 (Company # 961)		
<del>-</del>			Loveland Products, Inc.	Pay	
			P.O. Box 1286		
			Greeley, CO 80632 (Company # 34704)		
			NuFarm Limited Agent for: NuFarm Limited	Pay	
			P.O. Box 13439		
· · · · · · · · · · · · · · · · · · ·			RTP, NC 27709 (Company # 35935)		
Signature N	rushan Mandan	«	Name and Title N. Bhushan Mandava, Ph.D., Agent - United Ph	osphorus, inc	Date August 30, 20

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	DA	TA MATRIX			
Date August 30, 2007  Applicant's/Registrant's Name & Address  United Phosphorus, Inc. 630 Freedom Business Center, Suite 402 King of Prussia, PA 19406			EPA Reg No./File Symbol 70506-93	Page 6 of 7	
			Product Clopyralid Technical		
Ingredient Clopyralid (CAS# 1702-17-	-6)				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Acute Toxicity and Generic Data		CITE-ALL	Albaugh, INC. Agent for: Albaugh, Inc.	Pay	
			P.O. Box 2127		
			Valdosta, GA 31604 (Company # 42750)		
			Dow AgroSciences, LLC	Pay	
			9330 Zionsville Road 308/2E		
			Indianapolis, IN 46268 (Company # 62719)		
			Spray Drift Task Force	Pay	
			1900 K Street, N.W.		
-			Washington, D.C. 20006 (Company # 66607)		
			United Phosphorus, Inc.	Pay	
			423 Riverview Plaza		
		1	Trenton, NJ 08611 (Company # 70506)		
			NuFarm, Inc.	Pay	
			150 Harvester Drive Suite 200		
			Burr Ridge, IL 60527 (Company # 71368)		
Signature N. Blu	ustan Mandava	Name and Title N. Bhushan Mandava, Ph.D., Agent - United Ph	Date August 30, 200		

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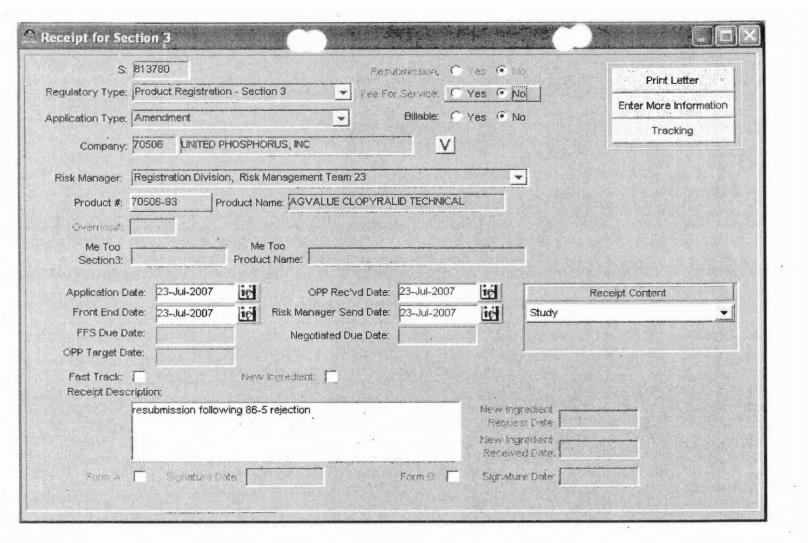
		DATA MATRIX			
Date August 30, 2007  Applicant's/Registrant's Name & Address  United Phosphorus, Inc. 630 Freedom Business Center, Suite 402 King of Prussia, PA 19406			EPA Reg No./File Symbol 70506-93	Page 7 of 7	
			Product Clopyralid Technical		
Ingredient Clopyralid (CAS# 1702-1	7-6)				
Guideline Reference Number	Guideline Study Name	Submitter	Status	Note	
Acute Toxicity and Generic Data		CITE-ALL	Outdoor Residential Exposure Task Force, LLC	Pay	
			1350 I Street, N.W.		
			Washington, D.C. 20005 (Company # 71754)	:	
			Agricultural Reentry Task Force, LLC	Pay	
			1350 I Street, N.W.		
			Washington, D.C. 20005 (Company # 71755)		
			FIFRA Endengered Species Task Force, LLC	Pay	
			1350 I Street, N.W.		
			Washington, D.C. 20005 (Company # 73989)		
			Residential Exposure Joint Venture (REJV)	Pay	
			900 17th Street, NW, Suite 300		
<del></del>			Washington, D.C. 20006 (Company # 74888)		
			Agricultural Handlers Exposure Task Force	Pay	
			P.O. Box 509		
		i	Mecon, MO 63552 (Company # 75234)		
Signature Name and Title N. Bhushan Mandava, Ph.D., Agent - United Phosphorus, Inc					Date August 30, 200

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Regulatory Type:	813410 Product Registratio		▼ Fee For Ser	vice: 6	- Canada Carana	4o	Print Letter  Enter More Information
Application Type: Company:		HOSPHORUS, INC	▼] Bil	able: •	Yes C 1	No.	Tracking
Product #:  Product #:  Me Too Section3:  Application Description	70506-93 Pr	n, Risk Management Te oduct Name: Me Too Product Name:	earn 23	ul-2007	ii		Receipt Content
Front End De FFS Due De OPP Target De	ate:	Risk Manager					
Fast Track: Receipt Desc	Analysis and the second second	New Ingredient.					
		r clopyralid technical		A Comment of the Comm	Nevy Ing	gredient est Date: gredient ed Date:	
				esseries de la constitución de l			

Jim

R-34



## MANDAVA ASSOCIATES, LLC

CONSULTANTS IN SCIENCE, TECHNOLOGY AND REGULATORY AFFAIRS

1730 M STREET, N.W., SUITE 906, WASHINGTON, DC 20036-4512

TELEPHONE: (202)-223-1424/1747 · TELEFAX: (202)-223-0141 · E-Mail: mandava@compuserve.com

#### HAND DELIVERED

July 9, 2007

Ms. Joanne I. Miller Product Manager 23 Herbicide Branch Registration Division (7505C) U.S. Environmental Protection Agency Washington, DC 20460

SUBJECT: Alternate Source for CLOPYRALID TECHNICAL

Active Ingredient: Clopyralid EPA Reg. No.: 70506-93

Registrant: United Phosphorus, Inc.

Dear Ms. Miller:

Clopyralid Technical (EPA Reg. No.: 70506-93) is registered by United Phosphorus, Inc. (UPI). According to label ingredient statement, the purity of active ingredient (as clopyralid) is 96% in Clopyralid Technical.

The registrant (UPI) is seeking an alternate source for Clopyralid Technical and the producer for proposed alternate source is United Phosphorus Ltd. We are submitting the following product chemistry data in support of the alternate source for Clopyralid Technical.

- 1) Volume 1: CLOPYRALID TECHNICAL: Group A Product Identity and Composition and Analysis. Product Properties Data in Support of FIFRA Registration. Data Requirement: 40 CFR § 158.155-180: OPPTS Test Guidelines 830.1000 1900; OPP Guideline Series 61 and 62; (Project Number: UPL-CLOPYR-TECH-PC-1); United Phosphorus, Inc.
- Volume 2: Preliminary Analysis of Five Representative Production Batches of Clopyralid Technical Grade Active Ingredient (TGAI) to Determine % Clopyralid and to Quantify its Associated Impurities. U.S. EPA OPPTS Test Guidelines 830.1700, 830. 1800 and EU 91/414/EEC, SANCO/3039/99 rev.4; (JRF Study Number: 6587); Jai Research Foundation.

- 3) Volume 2A CLOPYRALID TECHNICAL: Group A Product Identity and Composition. Product Properties Data in Support of FIFRA Registration. Data Requirement: 40 CFR § 158.155-180: OPPTS Test Guidelines 830.1000 1900; OPP Guideline Series 61 and 62; (Project Number: UPL-CLOPYR-TECH-PC-2); United Phosphorus, Inc.
- 4) Volume 3.1 Appearance (Colour, Physical State and Odour) of Clopyralid Technical: Data Requirement: OPPTS Test Guidelines 830.6302, 6303 and 6304; JRF Study Number: 6592; Jai Research Foundation.
- 5) Volume 3.2 pH of Clopyralid Technical: Data Requirement: OPPTS Test Guidelines 830.7000; JRF Study Number: 6593; Jai Research Foundation.
- 6) Volume 3.3 Tap Density of Clopyralid Technical: Data Requirement: Method: CIPAC MT 33; JRF Study Number: 6661; Jai Research Foundation.
- 7) Volume 3A CLOPYRALID TECHNICAL: Group B Physical and Chemical Properties. Product Properties Data in Support of FIFRA Registration. Data Requirement: 40 CFR § 158.190: OPPTS Test Guidelines 830.6302 7950; OPP Guideline Series 63; (Project Number: UPL-CLOPYR-TECH-PC-3); United Phosphorus, Inc.

We have enclosed a copy of the approved label for Clopyralid Technical (EPA Reg. No.: 70506-93) and the Confidential Statement of Formula (EPA Form 8570-4) for proposed alternate source product.

Since we unequivocally showed that, based on the product chemistry data, the proposed alternate source for Clopyralid Technical is the same as or substantially similar to the registered Clopyralid Technical (70506-93), we request you to approve the proposed alternate source (alternate formulation). Thank you for your ready cooperation.

Sincerely,

N. Bhushan Mandava, Ph.D., RAC Agent for United Phosphorus, Inc.

N. Rhishen Mandave

#### TRANSMITTAL DOCUMENT

#### NAME AND ADDRESS OF SUBMITTER:

United Phosphorus, Inc. 630 Freedom Business Center Suite 402 King of Prussia, PA-19406

#### REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

#### FIFRA Registration Application for:

Product Name:

Clopyralid Technical

Active Ingredient:

Clopyralid

Company Name:

United Phosphorus, Inc.

EPA Company Number:

70506

EPA File Symbol:

70506-93

#### TRANSMITTAL DATE:

July 9, 2007

#### LIST OF SUBMITTED STUDIES:

47178801

1) Volume 1:

CLOPYRALID TECHNICAL: Group A - Product Identity and Composition and Analysis. Product Properties Data in Support of FIFRA Registration. Data Requirement: 40 CFR § 158.155-180: OPPTS Test Guidelines 830.1000 - 1900; OPP Guideline Series 61 and 62; (Project Number: UPL-CLOPYR-TECH-PC-1); United Phosphorus, Inc.

**47183401** 2) Volume 2:

Preliminary Analysis of Five Representative Production Batches of Clopyralid Technical Grade Active Ingredient (TGAI) to Determine % Clopyralid and to Quantify its Associated Impurities. U.S. EPA OPPTS Test Guidelines 830.1700, 830. 1800 and EU 91/414/EEC, SANCO/3039/99 rev.4; (JRF Study Number: 6587); Jai Research Foundation.

47178803	3)	Volume 2A	CLOPYRALID TECHNICAL: Group A - Product Identity and Composition. Product Properties Data in Support of FIFRA Registration. Data Requirement: 40 CFR § 158.155-180: OPPTS Test Guidelines 830.1000 - 1900; OPP Guideline Series 61 and 62; (Project Number: UPL-CLOPYR-TECH-PC-2); United Phosphorus, Inc.
47178804	4)	Volume 3.1	Appearance (Colour, Physical State and Odour) of Clopyralid Technical: Data Requirement: OPPTS Test Guidelines 830.6302, 6303 and 6304; JRF Study Number: 6592; Jai Research Foundation.
47178805	5)	Volume 3.2	pH of Clopyralid Technical: Data Requirement: OPPTS Test Guidelines 830.7000; JRF Study Number: 6593; Jai Research Foundation.
47178806	6) .	Volume 3.3	Tap Density of Clopyralid Technical: Data Requirement: Method: CIPAC MT 33; JRF Study Number: 6661; Jai Research Foundation.
47178807	7)	Volume 3A	CLOPYRALID TECHNICAL: Group B – Physical and Chemical Properties. Product Properties Data in Support of FIFRA Registration. Data Requirement: 40 CFR § 158.190: OPPTS Test Guidelines 830.6302 - 7950; OPP Guideline Series 63; (Project Number: UPL-CLOPYR-TECH-PC-3); United Phosphorus, Inc.

#### COMPANY OFFICIAL:

N. Bhushan Mandava, Ph.D., RAC

Registration Agent for United Phosphorus, Inc.

#### COMPANY CONTACT:

N. Bhushan Mandava Mandava Associates, LLC 1730 M Street, N.W., Suite 906 Washington, D.C. 20036 (202) 223-1424/1747

<b>\$EPA</b>	United States Environmental Protection Agency Washington, DC 20460					_	egistration mendment opp Identifier ther			r Number		
		Application	on for Pe	esticide	- Sect	ion I						
1. Company/Product Nu 70506-93	mber			2. EPA Product Manager  Joanne I. Miller  None						Classifi	cation Restricted	
4. Company/Product (Na United Phosphoru	ime) s, Inc./Clopyralid Tech	nnical	ı	PM# 23							Nestilcle	
United Phosphoru 630 Freedom Bus King of Prussia, P	iness Center, Suite		1	6. Expedi (b)(i), my to: EPA Reg	product is	s simil	ar or iden	tical in c	ompositi	on and	d labeling	
			Secti	on - II							<u>.</u>	
Notification - Exp  Explanation: Use add  1) This application is for 2) Submittal of Product (3) The action code for th 4) Please direct all corre	response to Agency letter lain below. litional page(s) if necesses the approval of alternate so Chemistry data on Clopyrali	ry. (For section ource of Clopyrad Technical frossociates, LLC;	alid Technica m United Pho 1730 M Stre	dion II.) Il (EPA Regosphorus, Let, NW / Su	gency lette Me Too" A ther - Expl  No. 7050 td. which is	er date pplicat ain bel 6-93). s propo ashingt	ow.	sed as the	alternate	source		
			Section	on - III								
1. Material This Product	Will Be Packaged In:											
Child-Resistant Packaging Yes No Certification mus be submitted	V No  If "Yes" No. per  Certification must Unit Packaging wat container			olubie Pack es lo wgt	No. per container		2. Type o	Metal  Metal  Plastic  Glass  Paper  Other (Specify)				
3. Location of Net Conte	tail Containe	or ne		5. Loc	ation of La	bel Direct	ions					
6. Manner in Which Lab	el is Affixed to Product	Lithor Paper Stend	graph r glued siled		Other							
	<del></del>	<del></del>		on - IV		•						
1. Contact Point (Comp	lete items directly below	for identification	on of individ	ual to be c	ontacted, i	f nece	ssary, to p	rocess thi	s applica	tion.)		
Name N. Bhushan Mandava, Ph.D.			Title Agent for	for United Phosphorus, Inc.  Telephone No. (Include Area (202) 223-1424					Area Code			
Certific   certify that the statements   have made on this form as   acknowledge that any knowlingly false or misleading a   both under applicable law.			d all attachm atement may									
2. Signature			3. Title						ĺ			

Agent for United Phosphorus, Inc.

07/09/07

5. Date

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete.

4. Typed Name

N. Bhushan Mandava, Ph.D.

White - EPA File Copy (original)

Yellow - Applicant Copy



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

July 24, 2007

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

UNITED PHOSPHORUS, INC 630 FREEDOM BUSINESS CENTER, SUITE 402 KING OF PRUSSIA, PA 19406-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 23-JUL-07. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

July 19, 2007

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

UNITED PHOSPHORUS, INC 630 FREEDOM BUSINESS CENTER, SUITE 402 KING OF PRUSSIA, PA 19406-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 12-JUL-07. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document accepted. Please use these numbers in all future references to these documents.

If deficiencies were found which apply to individual accepted studies, they are listed below following the applicable MRID. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. Some individual documents were not acceptable, and all copies are being returned to you for correction for the reasons indicated below.

These rejected studies have been assigned separate identification numbers which are annotated on both the enclosed bibliography and the rejected document labels.

The rejected studies and their deficiencies are described below.

Rejected S	Study	y [02]:						
*	The	following page(s) i	n this	study is/are	illegibledue to	the poor	quality (	of the
photocopy	ing:_	191		_•				

### TRANSMITTAL DOCUMENT

### NAME AND ADDRESS OF SUBMITTER:

United Phosphorus, Inc. 630 Freedom Business Center Suite 402 King of Prussia, PA 19406

### REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

### FIFRA Registration Application for:

Product Name:

Clopyralid Technical

Active Ingredient:

Clopyralid

Company Name:

United Phosphorus, Inc.

EPA Company Number:

70506

EPA File Symbol:

70506-93

### TRANSMITTAL DATE:

July 9, 2007

### LIST OF SUBMITTED STUDIES:

47178801

1) Volume 1:

CLOPYRALID TECHNICAL: Group A - Product Identity and Composition and Analysis. Product Properties Data in Support of FIFRA Registration. Data Requirement: 40 CFR § 158.155-180: OPPTS Test Guidelines 830.1000 - 1900; OPP Guideline Series 61 and 62; (Project Number: UPL-

CLOPYR-TECH-PC-1); United Phosphorus, Inc.

Reject (02)

Volume 2:

2)

Preliminary Analysis of Five Representative Production Batches of Clopyralid Technical Grade Active Ingredient (TGAI) to Determine % Clopyralid and to Quantify its Associated Impurities. U.S. EPA OPPTS Test Guidelines 830.1700, 830. 1800 and EU 91/414/EEC, SANCO/3039/99 rev.4; (JRF Study Number: 6587); Jai Research Foundation.

47178803	3)	Volume 2A	CLOPYRALID TECHNICAL: Group A - Product Identity and Composition. Product Properties Data in Support of FIFRA Registration. Data Requirement: 40 CFR § 158.155-180: OPPTS Test Guidelines 830.1000 - 1900; OPP Guideline Series 61 and 62; (Project Number: UPL-CLOPYR-TECH-PC-2); United Phosphorus, Inc.
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### COMPANY OFFICIAL:

N. Bhushan Mandava, Ph.D., RAC

Registration Agent for United Phosphorus, Inc.

### **COMPANY CONTACT:**

N. Bhushan Mandava Mandava Associates, LLC 1730 M Street, N.W., Suite 906 Washington, D.C. 20036 (202) 223-1424/1747 A Jacket Already Exists for this Amendment

Please File the Amendment in the Jacket

And Check it out to the Assigned PM Waiting for data package.

71



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

July 16, 2007

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT OR PAY ON-LINE at www.Pay.Gov (See Below for Details)

OPP Decision Number: D-381191

EPA File Symbol or Registration Number: 70506-93

Product Name: Clopyralid Technical EPA Receipt Date: 12-Jul-2007 EPA Company Number: 70506

Company Name: UNITED PHOSPHORUS, INC

TIMOTHY M. FORMELLA UNITED PHOSPHORUS, INC 630 FREEDOM BUSINESS CENTER, SUITE 402 KING OF PRUSSIA, PA 19406-

SUBJECT: Receipt of Amendment Subject to Registration Service Fee

### Dear Registrant:

The Office of Pesticide Programs has received your application for Amendment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R34

NON-FAST-TRACK (INCLUDES CHANGES TO PRECAUTIONARY LABEL STATEMENTS; SOURCE CHANGES TO AN UNREGISTERED SOURCE);

Please remit payment in the amount of: \$ 3,150 to:

### By USPS:

USEPA Washington Finance Center Pesticide Registration Service Fee PO Box 360277 Pittsburgh, PA 15251 By Courier:

U.S. EPA Washington Finance Center Pesticide Registration Service Fee C/O Mellon Client Service Center 500 Ross Street, Room 670 Box 360277 Pittsburgh, PA 15251-6277

Attn: EPA Module Supervisor Telephone: (412) 236-2294

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

Effective November 1, 2006, fees may be paid on-line via credit card or electronic fund transfer. To submit a payment on-line, visit www.pay.gov. From the pay.gov home page, select "search by form name." From the next page, select "P," then click on "Pesticide Registration Improvement Act. Fee Payment" and complete the form, making certain to use the decision number and registration number on the invoice you receive from the Pesticide Program in the space provided.

You may be eligible for a full or partial waiver of the registration service fee if, for example, you qualify as a small business or are applying for a minor use, or if your application is soley associated with an IR-4 tolerance petition. Please be advised that if you intend to request a waiver, you must do so in writing within 15 days of receipt of this invoice instead of remitting the amount indicated above. OPP will not consider waiver requests after the registration service fee has been paid. Information regarding eligibility and how th request and document a fee waiver is available on the OPP Fee for Service web site at www.epa.gov/pesticides/fees.

Please send Registration Service Fee Waiver requests to:

By USPS:

Document Processing Desk (WAIVER) Office of Pesticide Programs (7504P) U.S. Environmental Protection Agency 1200 Pennsylvania Ave NW

Washington, DC 20460

By Courier:

Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency

Room S-4900 Potomac Yard

2777 S. Crystal Dr. Arlington, VA

A PRIA decision time review period will not start until a fee waiver is granted and/or the Agency receives certification that the outstanding fee has been paid. If the Agency does not receive certification of payment for this action or a fee waiver request within the next 45 days, the Agency will presume that you no longer want to pursue this action. The Agency will then initiate a process that may result in administrative withdrawal of this action.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman,

at (703) 305-6249.

Sincerely,

Front End Processing Staff

Teresa Cown

Information Technology & Resources Management Division

## Fee for Service {813410c~

This package includes the following	tor Division
New Registration  • Amendment	AD BPPD RD
Studies? Fee Waiver?	
volpay % Reduction:	Risk Mgr. 23
Receipt No. S-	813410
EPA File Symbol/Reg. No.	70506-93
Pin-Punch Date:	7/9/2007
This item is NOT subject t	to FFS action.
Action Code:	Parent/Child Decisions:
Requested: (24	
Granted: R34	
Amount Due: \$ 3,150 =	
X Inert Cleared for Intended Use RN	Uncleared Inert in Product
Reviewer: J. Miller	Date: <u>7- 16-09</u>
Remarks: Product chemistry	data to support e of technical AI



### United Phosphorus, Inc.

630 Freedom Business Center Suite 402 King of Prussia, PA 19406 www.uniphos.com

Tel: 610-491-2800 Fax: 610-491-2801

August 16, 2007

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mer

Joanne Miller (PM 23)
Document Processing Desk (FPL)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Re: Clopyralid Technical (EPA Reg. No. 70506-93)

Submission of Final Printed Labeling

Dear Ms. Miller:

United Phosphorus, Inc. received approval of an amendment to the subject label in your letter dated Sept. 20, 2005. Since my files do not have record of it, I am sending you a copy of the revised final printed labeling (revisions as required by your letter). This revised label has been neither printed nor released for shipment as of this date.

In addition to the changes you required in 2005, I am also making the following changes: change in company address and contact information, and change in emergency contact information.

Enclosed please find:

- EPA Form 8570-1
- One copy of the revised label

Please contact me if you have any questions.

Very truly yours,

Rebecca A. Clernmer Country and the state of the country of the state of the state

possible one or advis-

rebecca.clemmer@uniphos.com

Please read instructions on reverse before completing form Form Approved, OMB No. 2070-0060, Approval expires 5-31-98 OPP Identifier Number Registration **United States** Amendment **Environmental Protection Agency** 2705068 Other X Washington, DC 20460 Application for Pesticide - Section I 1. Company/Product Number 2. EPA Product Manager 3. Proposed Classification 70506-93 J. Miller 4. Company/Product (Name) PM# None Restricted United Phosphorus, Inc/Clopyralid Technical 23 5. Name and Address of Applicant (Include ZIP Code) 6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling United Phosphorus, Inc. 630 Freedom Business Center, Suite 402 King of Prussia, PA 19406 EPA Reg No. Check if this is a new address **Product Name** Section - II Amendment - Explain below Final printed labels in response to Agency letter dated Sept. 20, 2005 Resubmission in response to Agency letter dated "Me Too" Application Notification - Explain below Other - Explain below Explanation: Use additional page(s) if necessary. (For Section I and Section II.) Section III 1. Material This Product Will be Packaged in: Water Soluble Packaging Type of Container Child-Resistant Packaging Unit Packaging Metal Yes Yes Yes Plastic No No No Glass \*Certification must If "Yes" No. per No. per Paper If "Yes" Unit Packaging wgt. container container Package wgt be submitted Other (Specify) 3. Location of Net Contents Information 4. Siże(s) Retail Container 5. Location of label directions Label Container On Label On Label accompanying product 6. Manner in Which Label is Affixed to Product Lithograph Other Paper glued Stenciled Section IV 1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) Telephone No. (Include Area Code) Title

Regulatory Manager

Regulatory Manager

August 16, 2007

3. Title

5. Date

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.

Rebecca A. Clemmer

both under applicable law

2. Signature

4. Typed Name

Rebecca A. Clemmer

White - EPA File Copy (Original) Yellow - Applicant Copy

6. Date Application

(Stamped)

Received

610-491-2828

### **Clopyralid Technical**

### **ACTIVE INGREDIENT:**

Clopyralid: 3,6-dichloro-2-pyridinecarboxylic acid	96.0%
INERT INGREDIENTS:	4.0%

### KEEP OUT OF REACH OF CHILDREN DANGER

	DANGER
	FIRST AID
If in eyes:	<ul> <li>Hold eye open and rinse slowly with a steady, gentle stream of water for 15-20 minutes.</li> </ul>
	<ul> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> </ul>
	<ul> <li>Call a poison control center or physician for treatment advice.</li> </ul>
If swallowed:	<ul> <li>Call a physician or poison control center immediately for treatment advice.</li> </ul>
	<ul> <li>Have person sip a glass of water if able to swallow.</li> </ul>
	<ul> <li>DO NOT induce vomiting unless told to do so by poison control</li> </ul>
	center or physician.
	<ul> <li>Do not give anything by mouth to an unconscious person.</li> </ul>
If inhaled:	Move person to fresh air.
	• If person is not breathing, call 911 or an ambulance, then give
	artificial respiration, preferably, mouth-to-mouth, if possible.
	<ul> <li>Call a poison control center or physician for treatment advice.</li> </ul>
If on skin or	Take off contaminated clothing.
clothing:	<ul> <li>Wash skin with plenty of water for 15-20 minutes.</li> </ul>
	<ul> <li>Call a poison control center or physician for treatment advice.</li> </ul>
Note to Physician:	Probable mueosal damage may contraindicate the use of gastric lavage.
Have the product of	container or label with you when calling a poison control center or doctor,
or going for treatm	ent.
For chemical emerated 424-9300.	rgency: spill, leak, fire, exposure or accident, call CHEMTREC at 1-800-

See side panel for additional precautionary statements.

### Manufactured For:

630 Freedom Business Center, Suite 402 King of Prussia, PA 19406

1-800-4386071 • www.upi-usa.com

EPA Reg. No. 70506-93 EPA Est. No.

Net Weight:

## PRECAUTIONARY STATEMENTS Hazard to Humans and Domestic Animals DANGER

Corrosive. Causes irreversible eye damage. Harmful if absorbed through skin or inhaled. Do not get in eyes or on skin and clothing. Wear goggles or face shield when handling. Avoid breathing dust. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

### **ENVIRONMENTAL HAZARDS**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

#### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product may only be formulated into manufacturing-use herbicide products or end-use herbicide products for the following uses:

### Agricultural Uses

Asparagus, barley, broccoli, broccoli raab, Brussels sprouts, cabbage, canola, cauliflower, Chinese cabbage, Chinese broccoli, collards, corn, fallow land, garden beets, grasses, kale, kohlrabi, mint, mizuna, mustard greens, mustard spinach, oats, pasture, rangeland, rape greens, spinach, stone fruits, sugar beets, tree plantations, turnips, and wheat. This product may be used to formulate products for specific use(s) not listed on this label, except residential turf, if the formulator, user group or grower has complied with U.S. EPA submission requirements regarding the support of such use(s). Consult United Phosphorus, Inc. for instructions for formulation and other information.

#### Non-Agricultural Uses

For manufacture of herbicides for use only on non-residential turf such as athletic and recreational sports fields, cemeteries, golf courses, industrial manufacturing and storage sites, non-cropland, parks, rights-of-way, sod farms and roadsides; grass grown for seed; select ornamental plantings in landscapes and nurseries, forest sites; CRP acres. This product may be used to formulate products for specific use(s) not listed on this label, except residential turf, if the formulator, user group or grower has complied with U.S. EPA submission requirements regarding the support of such uses(s). Consult United Phosphorus, Inc. for instructions for formulation and other information.

This product must not be formulated into manufacturing-use products or end-use products for use on residential turf.

If the product is labeled for reformulation into products bearing labeling for turf applications other than residential turf, the formulated product label must contain the following statements:

- Do not use on residential turf
- Do not send clippings to a compost facility
- Do not cellect grass clippings for mulch or compost
- Applicator must give notice to landowners/property managers to not use grass clippings for composting.

#### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store in a cool, dry, well-ventilated area.

**PESTICIDE DISPOSAL:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by procedures approved by state and local authorities.

## CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

United Phosphorus, Inc. warrants that at the time of delivery, this product will conform to its chemical description on the label, that it is reasonably fit for the purposes referred to in the Directions for use, that it will pass without objection in the trade under the contract description, that the seller will convey title hereto, and that such product will be delivered free from any lawful security interest, lien or encumbrance.

This is the only warranty made on this product. UNITED PHOSPHORUS, INC. EXPRESSLY DISCLAIMS ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND, EXCEPT AS SET FORTH IN THE ABOVE PARAGRAPH, ANY OTHER EXPRESS OR IMPLIED WARRANTIES. BUYER ACKNOWLEDGES THE USE OF ITS OWN INDEPENDENT SKILL AND EXPERTISE IN THE SELECTION AND USE OF THE PRODUCT AND DOES NOT RELY ON ANY ORAL OR WRITTEN STATEMENTS OR REPRESENTATIONS.

Rev. 8/07



### United Phosphorus, Inc.

630 Freedom Business Center, Suite 402 King of Prussia, PA 19406 (610) 491-2814 (phone) (610) 491-2810 (fax)

August 9, 2007

Joanne Miller, PM #23 Office of Pesticide Programs U.S. Environmental Protection Agency 1200 Pennsylvania Avenue, NW Washington, DC 20460

SUBJECT: Authorization Letter

Dear Ms. Miller

This letter is to authorize the following party to act on behalf of United Phosphorus Inc. as our agent to represent us before the United States Environmental Protection Agency (EPA) in regards to all matters pertaining to the registration of an alternate source for Clopyralid Technical (EPA Reg. # 70506-93). This authorization is specific to this regulatory action, which was submitted to the Agency on July 9, 2007.

MANDAVA ASSOCIATES, LLC 1730 M Street, N.W. Suite 906 Washington, DC 20036-4510 Telephone: (202) 223-1424

Fax: (202) 223-0141

E-Mail: Mandava@compuserve.com

Contact Person: N. Bhushan Mandava, Ph.D.

We acknowledge that all correspondence from EPA will be sent to our agent at the address listed above.

This appointment is to remain in effect until revoked by us in writing.

Sincerely,

David L. Olson

Director, Regulatory Affairs daye.olson@uniphos.com



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

JUL 27 200

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

United Phosphorus Inc. c/o N. Bhushan Mandava Ph.D. Mandava Associates, LLC 1730 M Street NW Washington, DC 20036

Gentlemen:

Subject:

New Source of Active Ingredient

Clopyralid Technical

EPA Registration No. 70506-93

Your application of July 9, 2007 was been found to be incomplete (deficiencies are outlined below). Failure to submit the missing information within 75 days will result in the need to negotiate a new latest completion date for the subject action.

Before we can complete processing of the subject application, you must comply the following:

- 1. Submit a notarized letter on company letter head authorizing N. Bhushan Mandava Ph.D. to handle all registration matters for the subject product.
- 2. Adding a new unregistered source of active ingredient is subject to data compensation. You must comply with Title 40 Code of Federal Regulations (CFR) Part 152 Subpart E Procedures to Ensure Protection of Data Submitter's Rights by choosing the Cite-All or the Selective Methods of Support. Submit a Certificate with Respect to Citation of Data (EPA Form 8570-34) and a Data Matrix (EPA Form 8570-27)

Please submit this missing information to Joanne Miller by:

- 1) E-mail (Miller.Joanne@epa.gov)
- 2) Fax (703-308-1825)
- 3) Hand deliver or next day delivery at:

Joanne Miller, Room number 4900 U.S. EPA Registration Division (7505P) One Potomac Yard (South Building) 2777 S. Crystal Drive Arlington, VA 22202 Thank you for your attention to this matter.

If you have any questions concerning this letter please contact Mr. James Stone at 703-305-7391.

Sincerely yours,

Joanne I. Miller

Product Manager (23)

Herbicide Branch

Registration Division (7505P)

ranne J. Miller

INFAC

# Material to be added to a Mini-Jacket (in the case where an e-Jacket exists)

	Reg. No. 10506-93
	Send to SIG: check box □
This ma	aterial is:
matthe The	New CSF Notification Final Printed Label Other:  tructions: Attach this notice on top of the terial. It must be clipped all together and re should be NO STAPLES in the material. In give the material with this coversheet to ff in the Information Services Center (Room 1).
Rev	viewer's Name: J,m She
Pho	one: <u>305-739/</u> Division: <u>RD</u>
Dat	e: 6/21/06



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

JUN 2 1 2008

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Rebecca A Clemmer United Phosphorus Inc 423 Riverview Plaza Trenton, NJ 08611

Dear Ms. Clemmer:

Subject: Storage Stability and Corrosion Characteristic Studies

Clopyralid Technical

EPA Registration No. 70506-93

Clopyr Ag

EPA Registration No. 70506-94

Your Submission Dated April 7, 2006

The subject Storage Stability and Corrosion Characteristic Studies are acceptable.

If you have any questions concerning this letter, please contact Mr. James Stone at 703-305-7391. For your information, enclosed is a copy of the scientific reviews.

Sincerely yours,

√oanne I. Miller

Product Manager (23)

Herbicide Branch

Registration Division (7505P)

vanne S. Miller

Enclosure

**DATE OUT: DATE:** 06/02/06

SUBJECT: FEE: PRODUCT CHEMISTRY REVIEW OF MP [ ] EP [X ]

**DP BARCODE No.:** 328809 **File Symbol No.**: 70506-93 **PRODUCT NAME:** AGVALUE CLOPYRALID TECHNICAL

COMPANY: UNITED PHOSPHORUS INC.

FOOD USE [] INTEGRATED FORMULATION []

**PCC:** 117403 **Decision No.** 367092

FROM:

Indira Gairola, Chemist

Product Chemistry Team

Technical Review Branch/RD (7505P)

TO:

Joanne Miller/James Stone PM 23

Herbicide Branch/RD(7505P)

### INTRODUCTION:

UNITED PHOSPHORUS INC has submitted Storage Stability Data and Corrosion Characteristic study (MRID# 468105-01) for the subject product AGVALUE CLOPYRALID TECHNICAL that contains active ingredient Clopyralid.

SBO 61121CD.

#### SUMMARY OF FINDINGS:

- 1. The submitted Storage Stability and Corrosion Characteristics data for the subject product AGVALUE CLOPYRALID TECHNICAL reviewed are for 0, 3, 6, 9 and 12 months at room temperature.
- 2. The Storage Stability and Corrosion Characteristics study was conducted in accordance with the requirements of U.S. Environmental Protection Agency Good Laboratory Practice 40 CFR § 160, FIFRA.
- 3. The study was accompanied by Quality Assurance statement 40 CFR § 160.
- 4. The samples were stored in original containers at warehouse conditions for 12 months at ambient temperatures.
- The samples were analyzed by HPLC Method with UV detection Zorbax SB-C8, 5μm, 4.6×150mm Column with auto injection and UV detection at 230 nm. Mobile Phase was 55/45/0.04 (v/v/v) Methanol / water/orthophosphoric acid.

- 5. Average recovery of active ingredient Clopyralid at the end of 3, 6, 9 &12 month period ranged from 100.94%-101.85% (Average 101.46%) from an initial of 101.03% at the end of 12 month period. Overall average recovery of the active ingredient in the sample in original containers at ambient temperatures was acceptable.
- There were no observed changes to the original containers, the containers showed
  no sign of fogging, discoloration, distortion, or cracking during the course of
  study under ambient conditions.
- 8. Appropriate table of recovery with results, chromatograms and calculations are included with this submission.

### **CONCLUSIONS:**

TRB has reviewed the aforementioned Data and concludes:

- 1. Results of Storage Stability data (830.6317) and Corrosion Characteristics (830.6320) showed acceptable recovery of the active ingredient in the sample.
- The submitted Storage Stability data and Corrosion Characteristics studies for the subject product AGVALUE CLOPYRALID TECHNICAL completely fulfill the requirements of OPPTS test guidelines 830.6317and 830.6320 respectively

Form Approved, OMB No. 2070-0060, Approval expires 5-31-98 Please read instructions on reverse before completing form OPP Identifier Number Registration **United States** Amendment 274969 **Environmental Protection Agency** Other Washington, DC 20460 Application for Pesticide - Section I Company/Product Number 2. EPA Product Manager 3. Proposed Classification 70506-94 J. Miller 4. Company/Product (Name) PM# Restricted None United Phosphorus, Inc/Clopyr Ag 23 5. Name and Address of Applicant (Include ZIP Code) 6. Expedited Review. In accordance with FIFRA Section 3(c)(3) United Phosphorus, Inc. (b)(i), my product is similar or identical in composition and labeling 423 Riverview Plaza to: Trenton, NJ 08611 EPA Reg No. Check if this is a new address Product Name Section - II Amendment - Explain below Final printed labels in response to Agency letter dated Resubmission in response to Agency letter dated "Me Too" Application Notification - Explain below Other - Explain below Explanation: Use additional page(s) if necessary. (For Section I and Section II.) Submission of storage stability and corrosion characteristics testing in response to EPA Notice of Pesticide Registration dated 5/6/03. Section III 1. Material This Product Will be Packaged in: Child-Resistant Packaging Unit Packaging Water Soluble Packaging Type of Container Yes Yes Metal Yes Plastic Nο Νo Nο Glass \*Certification must No. per If "Yes" No. per If "Yes" Paper Unit Packaging wgt. be submitted container Package wgt container Other (Specify) 3. Location of Net Contents Information 4. Size(s) Retail Container Location of label directions Label Container On Label On Label accompanying product 6. Manner in Which Label is Affixed to Product Lithograph Other Paper glued Stenciled Section IV Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) Title Telephone No. (Include Area Code) Rebecca A. Clemmer 609-392-8200 Regulatory Affairs Manager Certification Date Application Received I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law (Stamped) 2. Signature Regulatory Affairs Manager 4. Typed Name 5. Date Rebecca A. Clemmer April 7, 2006

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White - EPA File Copy (Orgina) Yellow - Applicant Copy



## **United Phosphorus, Inc.**

423 Riverview Plaza Trenton, NJ 08611 (609) 392-8200 x 1018 (phone) (609) 392-0073 (fax)

Rebecca A. Clemmer Regulatory Affairs Manager

April 7, 2006

Joanne Miller (PM 23) Document Processing Desk Office of Pesticide Programs (7504C) U.S. Environmental Protection Agency 1801 Bell Street Arlington, VA 22202

Re:

Submission of Storage Stability Studies

Clopyralid Technical (EPA Reg. No. 70506-93)

Clopyr Ag (EPA Reg. No. 70506-94)

Dear Ms. Miller:

Enclosed please find the following studies, which were required as a condition of registration:

46810501

Clopyralid Technical, Storage Stability and Corrosion Characteristics. OPP Guidelines

830.6317 and 830.6320. Jai Research Foundation, March 10, 2006. Study No. 15937.

46810502 Clopyr Ag, Storage Stability and Corrosion Characteristics. OPP Guidelines 830.6317 and 830.6320. Jai Research Foundation, March 10, 2006. Study No. 15888.

Please contact me if you have any questions.

Very truly yours,

Rebecca A. Clemmer

rclemmer@upi-usa.com

